blood or blood component, or other information related to when and how a donation is at risk of transmitting a relevant transfusion-transmitted infection. It may also include evidence related to the effectiveness of manufacturing steps (for example, the use of pathogen reduction technology) that reduce the risk of transmission of the relevant transfusion-transmitted infection by blood, blood components, or blood derivatives, as applicable.

(b) *Testing using one or more licensed, approved, or cleared screening tests.* To perform testing for evidence of infection due to relevant transfusion-transmitted infections as required in paragraph (a) of this section, you must use screening tests that FDA has licensed, approved, or cleared for such use, in accordance with the manufacturer's instructions. You must perform one or more such tests as necessary to reduce adequately and appropriately the risk of transmission of relevant transfusion-transmitted infections.

(c) *Exceptions to testing for dedicated donations, medical devices, and samples.* * * *

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(e) *Further testing.* You must further test each donation, including autologous donations, found to be reactive by a donor screening test performed under paragraphs (a) and (b) of this section using a licensed, approved, or cleared supplemental test, when available. If no such supplemental test is available, you must perform one or more licensed, approved, or cleared tests as adequate and appropriate to provide additional information concerning the reactive donor's infection status. Except:

(1) For autologous donations:

(i) You must further test under this section, at a minimum, the first reactive donation in each 30 calendar day period; or

(ii) If you have a record for that donor of a positive result on further testing performed under this section, you do not have to further test an autologous donation.

(2) You are not required to perform further testing of a donation found to be reactive by a treponemal donor screening test for syphilis.

* * * * *

§ 610.41 Donor deferral.

(a) You, an establishment that collects human blood or blood components, must defer donors testing reactive by a screening test for evidence of infection due to a communicable disease agent(s) listed in § 610.40(a) or reactive for a serological test for syphilis under § 610.40(i), from future donations of human blood and blood components, except:

(1) You are not required to defer a donor who tests reactive for anti-HBc or anti-HTLV, types I or II, on only one occasion. When a supplemental (additional, more specific) test for anti-HBc or anti-HTLV, types I and II, has been approved for use under § 610.40(e) by FDA, such a donor must be deferred;

(2) A deferred donor who tests reactive for evidence of infection due to a communicable disease agent(s) listed in § 610.40(a) may serve as a donor for blood or blood components shipped or used under § 610.40(h)(2)(ii);

(3) A deferred donor who showed evidence of infection due to hepatitis B surface antigen (HBsAg) when previously tested under § 610.40(a), (b), and (e) subsequently may donate Source Plasma for use in the preparation of Hepatitis B Immune Globulin (Human) provided the current donation tests nonreactive for HBsAg and the donor is otherwise determined to be suitable;

(4) A deferred donor, who otherwise is determined to be suitable for donation and tests reactive for anti-HBc or for evidence of infection due to HTLV, types I and II, may serve as a donor of Source Plasma;

(5) A deferred donor who tests reactive for a communicable disease agent(s) described under § 610.40(a) or reactive with a serological test for syphilis under § 610.40(i), may serve as an autologous donor under § 610.40(d).

(b) A deferred donor subsequently may be found to be suitable as a donor of blood or blood components by a requalification method or process found acceptable for such purposes by FDA. Such a donor is considered no longer deferred.

(c) You must comply with the requirements under §§ 610.46 and 610.47 when a donor tests reactive by a screening test for HIV or HCV required under § 610.40(a) and (b), or when you are aware of other reliable test results or information indicating evidence of HIV or HCV infection.

[66 FR 31164, June 11, 2001, as amended at 72 FR 48798, Aug. 24, 2007]

EFFECTIVE DATE NOTE: At 80 FR 29897, May 22, 2015, § 610.41 was amended as follows, effective May 23, 2016:

a. In paragraph (a) introductory text, remove ''communicable disease agent(s) listed in § 610.40(a) or reactive for a serological test for syphilis under § 610.40(i)'' and add in its place ''relevant transfusion-transmitted infection(s) under § 610.40(a)'';

b. Revise paragraph (a)(1);

c. In paragraph (a)(2), remove ''communicable disease agent(s) listed in'' and add in its place ''relevant transfusion-transmitted infection(s) under'';

d. In paragraphs (a)(3) and (4), remove ''suitable'' and add in its place ''eligible'';

e. In paragraph (a)(5), remove ''communicable disease agent(s) described under § 610.40(a) or reactive with a serological test for syphilis under § 610.40(i)'' and add in its place ''relevant transfusion-transmitted infections(s) under § 610.40(a)''; and

f. In paragraph (b), remove ''suitable'' and add in its place ''eligible''.

For the convenience of the user, the added and revised text is set forth as follows:

§ 610.41 Donor deferral.

(a) * * *

(1) You are not required to defer a donor who tests reactive for anti-HBc or anti-HTLV, types I and II, on only one occasion. However, you must defer the donor if further testing for HBV or HTLV has been performed under § 610.40(e) and the donor is found to be positive, or if a second, licensed, cleared, or approved screening test for HBV or HTLV has been performed on the same donation under § 610.40(a) and is reactive, or if the donor tests reactive for anti-HBc or anti-HTLV, types I and II, on more than one occasion;

* * * * *

§ 610.42 Restrictions on use for further manufacture of medical devices.

(a) In addition to labeling requirements in subchapter H of this chapter, when a medical device contains human blood or a blood component as a component of the final device, and the human blood or blood component was found to be reactive by a screening test performed under § 610.40(a) and (b) or reactive for syphilis under § 610.40(i), then you must include in the device labeling a statement of warning indicating that the product was manufactured from a donation found to be reactive by a screening test for evidence of infection due to the identified communicable disease agent(s).

(b) FDA may approve an exception or alternative to the statement of warning required in paragraph (a) of this section based on evidence that the reactivity of the human blood or blood component in the medical device presents no significant health risk through use of the medical device.

[66 FR 31164, June 11, 2001]

EFFECTIVE DATE NOTE: At 80 FR 29897, May 22, 2015, § 610.42 was amended by removing ''or reactive for syphilis under § 610.40(i)''; and removing ''communicable disease agent(s)'' and adding in its place ''relevant transfusion-transmitted infection(s)'', effective May 23, 2016.

§ 610.44 Use of reference panels by manufacturers of test kits.

(a) When available and appropriate to verify acceptable sensitivity and specificity, you, a manufacturer of test kits, must use a reference panel you obtain from FDA or from an FDA designated source to test lots of the following products. You must test each lot of the following products, unless FDA informs you that less frequent testing is appropriate, based on your consistent prior production of products of acceptable sensitivity and specificity:

(1) A test kit approved for use in testing donations of human blood and blood components for evidence of infection due to communicable disease agents listed in § 610.40(a); and

(2) Human immunodeficiency virus (HIV) test kit approved for use in the diagnosis, prognosis, or monitoring of this communicable disease agent.

(b) You must not distribute a lot that is found to be not acceptable for sensitivity and specificity under § 610.44(a). FDA may approve an exception or alternative to this requirement. Applicants must submit such requests in writing. However, in limited circumstances, such requests may be made orally and permission may be given orally by FDA. Oral requests and approvals must be promptly followed by written requests and written approvals.

[66 FR 31164, June 11, 2001]

EFFECTIVE DATE NOTE: At 80 FR 29897, May 22, 2015, § 610.44(a)(1) was amended by removing ''communicable disease agents listed in'' and adding in its place ''relevant transfusion-transmitted infections under''; and in paragraph (a)(2) removing ''communicable